Attorney's Docket No.: 17109-013001/923 Applicant: Rene Gantier et al.

Serial No.: 10/658,355 Filed : September 8, 2003

Election and Preliminary Amendment

REMARKS

A check for the fee for a five month extension of time accompanies this response. Any other fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 1-67 and 79-89 are pending in this application. Claims 1, 17, 19, 21, 25, 27, 28, 34, 37, 39, 41, 43, 45, 47 and 51 and claims 81-89 for clarity and to ensure proper dependency. Claims 68-78, which are drawn to non-elected subject matter, are cancelled without prejudice or disclaimer. Applicant reserves the right to file divisional applications to the non-elected subject matter. Claims that do not read on the elected species are retained for possible rejoinder upon allowance of a generic claim. Claims 1, 28 and 51, for example, are generic.

Traverse of Election of species

Applicant respectfully traverses the election of species as between methods in which LEADS are produced, and dependent claims that recite additional steps for production of super-LEADS. The Examiner urges that these are species because a different method is employed to arrive at each type of mutant protein.

Applicant respectfully submits that this is not correct. Methods in which LEADS are produced and dependent claims that recited additional steps for production of super-LEADS are related as genus/species, not as separate species. The super-LEADS are produced from the LEADS by first making LEADS, identifying proteins and loci in the target proteins among the LEADS that exhibit a desired modified property or activity, and then based upon the identified loci (is-HITS preparing polypeptides that contain two or more of these is-HITS to produce candidate super-LEADS. The method of producing super-LEADS includes the steps for producing LEADS plus additional steps. Thus, the methods for producing super-LEADS is a species of the generic method of claims directed to methods for producing LEADS.

Hence, Claims 1, 28 and 51, for example, are generic claims that are directed to methods for producing LEADS, which are modified proteins that differ from a target protein in one position. Claims 6 and 33, for example, are directed to the methods of claim 1 and 28, respectively, in which the LEADS are further modified to produce super-LEADS that contain two or more modifications compared to a target protein. Thus, a common method, the

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method of claims 1, 28 or 51, not a different method, is employed in arriving arrive at each type of mutant protein.

In addition, the number of mutations introduced into a super-LEAD is a function of the number of hits (LEADS) identified for any target protein and property or activity. It makes no sense to select, as a species, the number of hits, which is a function of the particular target and is an outcome of practice of the method. Therefore, election of the particular number of hits (LEADS), upon which super-LEADS are based, that will be discovered upon application of the method, is not appropriate nor a proper species.

Furthermore, if the methods of claims 1 and 28 are deemed allowable, the methods of claims 6 and 33 are necessarily allowable, since each includes the steps of the independent claim upon which each depends.

If this election of species is maintained, and a patent with claims to the methods of claims 6 and/or 33 were to issue, the Office will be precluded from finding obviousness-type double patenting as between such patent and a later issuing patent that includes claims to the methods of 1, 28 and/or 51. See MPEP 806, paragraph 3, which states:

[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Since, if restriction is required by the Office double patenting cannot be held, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

35 U.S.C.121, third sentence, provides that wherein the Office requires restriction, the patent of either the parent or any divisional application thereof conforming to the requirement cannot be used as a reference against the other. This apparent nullification of double patenting as ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restriction where the claims define essentially the same inventions in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

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In view of the above, reconsideration and withdrawal of the requirement for election of "species" as between the methods for producing LEADS and the methods that further comprise additional steps for producing super-LEADS, and examination of the application on the merits are respectfully requested.

Respectfully Submitted,

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